

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH
CAROLINA WESTERN DIVISION**

AQUESTIVE THERAPEUTICS, INC.

Plaintiff,

v.

BIODELIVERY SCIENCES
INTERNATIONAL, INC.,

Defendant.

Civil Action No. 5:19-CV-505-BO

**MEMORANDUM IN SUPPORT OF AQUESTIVE'S MOTION TO
DISMISS BDSI'S THIRD AMENDED COUNTERCLAIM AND TO
STRIKE BDSI'S FOURTH AND SIXTH AFFIRMATIVE
DEFENSES**

James F. Hibey
STEPTOE & JOHNSON LLP
1330 Connecticut Avenue, NW
Washington, DC 20036
(202) 429-6407
jhibey@steptoe.com
kcappaert@steptoe.com

John L. Abramic
Anna M. Targowska
STEPTOE & JOHNSON LLP
227 West Monroe St., Suite 4700
Chicago, IL 60606
(312) 577-1264
jabramic@steptoe.com
atargowska@steptoe.com

Jamie L. Lucia
STEPTOE & JOHNSON LLP
One Market Plaza
Spear Tower, Suite 3900
San Francisco, CA 94105

(415) 365-6711
jlucia@steptoe.com

E. Bradley Evans
NC State Bar No. 28515
Email: ebe@wardensmith.com
Joseph A. Schouten
NC State Bar No. 39430
Email: jas@wardensmith.com
WARD & SMITH, P.A.
Post Office Box 8088
Greenville, NC 27835-8088
Telephone: (252) 215-4025
Facsimile: (252) 215-407

*Attorneys for Plaintiff
Aquestive Therapeutics, Inc.*

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	BACKGROUND	3
	A. BDSI'S THIRD COUNTERCLAIM.....	3
	1. Allegations concerning the "Uniformity Requirements"	4
	2. Allegations concerning "Films and Micrographs"	5
	B. BDSI'S FOURTH AND SIXTH AFFIRMATIVE DEFENSES.....	6
III.	LEGAL STANDARD.....	6
	A. Motion to Dismiss Standard under Rule 12(b)(6).....	6
	B. Heightened Inequitable Conduct Pleading Standard under Rule 9(b)	7
	C. Motion to Strike Standard under Rule 12(f)	8
IV.	BDSI'S THIRD COUNTERCLAIM SHOULD BE DISMISSED	9
	A. BDSI's Allegations Regarding "Uniformity Requirements" Do Not State a Claim for Inequitable Conduct	10
	1. BDSI's allegations do not meet the materiality prong.....	10
	2. BDSI's allegations do not meet the intent prong	13
	B. BDSI's Allegations Regarding "Films and Micrographs" Do Not State a Claim for Inequitable Conduct	14
	1. BDSI's allegations do not meet the materiality prong.....	14
	2. BDSI's allegations do not meet the intent prong	17
V.	BDSI'S FOURTH AND SIXTH AFFIRMATIVE DEFENSES OF UNENFORCEABILITY AND UNCLEAN HANDS SHOULD BE STRICKEN	17
VI.	CONCLUSION.....	18

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Ashcroft v. Iqbal</i> , 556 U.S. 662 (2009)	7
<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544 (2007)	6, 7, 8
<i>Collaboration Props., Inc. v. Tandberg ASA</i> , 2007 WL 205065 (N.D. Cal. Jan. 25, 2007)	9, 18
<i>Consol. Aluminum Corp. v. Foseco Int’l Ltd.</i> , 910 F.2d 804 (Fed. Cir. 1990)	15
<i>Cordis Corp. v. Boston Scientific Corp.</i> , 188 F. App’x 984 (Fed. Cir. 2006)	15
<i>Exergen Corp. v. Wal-Mart Stores, Inc.</i> , 575 F.3d 1312 (Fed. Cir. 2009)	<i>passim</i>
<i>Illumina, Inc. v. BGI Genomics Co.</i> , 2020 WL 571030 (N.D. Cal., Feb. 5, 2020)	<i>passim</i>
<i>Innogenics, N.V. v. Abbott Labs.</i> , 512 F.3d 1363 (Fed. Cir. 2008)	10
<i>Pfizer Inc. v. Sandoz Inc.</i> , No. CV 12-654-GMS/MPT, 2013 WL 5934635 (D. Del. Nov. 4, 2013)	14
<i>Phillips v. LCI Int’l, Inc.</i> , 190 F.3d 609 (4th Cir. 1999)	16
<i>Racick v. Dominion Law Assoc.</i> , 270 F.R.D. 228 (E.D.N.C. 2010)	8
<i>Reaves v. Hagel</i> , 2013 WL 5674981 (E.D.N.C. Oct. 17, 2013)	16
<i>Rothman v. Target Corp.</i> , 556 F.3d 1310 (Fed. Cir. 2009)	10, 14, 15
<i>Therasense, Inc. v. Becton, Dickinson and Co.</i> , 649 F.3d 1276 (Fed. Cir. 2011) (<i>en banc</i>)	<i>passim</i>
<i>Veney v. Wyche</i> , 293 F.3d 726 (4th Cir. 2002)	16

<i>Xitronix Corp. v. KLA-Tencor Corp.</i> , No. 08-cv-723-SS, 2010 WL 11507169 (W.D. Tex. Oct. 27, 2010).....	14
--	----

Other Authorities

Federal Rule of Civil Procedure 12(b)(6)	6
Federal Rule of Civil Procedure 12(f).....	8
Federal Rules of Civil Procedure Rule 9(b).....	<i>passim</i>

Pursuant to Federal Rules of Civil Procedure 12(b)(6) and 12(f), Plaintiff Aquestive Therapeutics, Inc. (“Aquestive”) respectfully requests that the Court dismiss Defendant BioDelivery Sciences International, Inc.’s (“BDSI”) Third Counterclaim for “Declaratory Judgment of Unenforceability” of Aquestive’s asserted U.S. Patent No. 8,765,167 (“the ’167 patent”) and that the Court strike BDSI’s Fourth and Sixth Affirmative Defenses of unenforceability and unclean hands. *See* Dkt. 31 (BDSI’s Answer to Complaint and Amended Counterclaims) (“Amended Counterclaims”), at 12-13, 25-41.

BDSI’s Third Counterclaim, which alleges unenforceability due to purported inequitable conduct, should be dismissed because BDSI’s allegations do not meet the heightened pleading standard for inequitable conduct under Rule 9(b) of the Federal Rules of Civil Procedure. Similarly, BDSI’s Fourth and Sixth Affirmative Defenses of unenforceability and unclean hands should be stricken because they also fail to meet the heightened pleading standard of Rule 9(b).

I. INTRODUCTION

BDSI’s Amended Counterclaims reflect BDSI’s second attempt to insert a baseless inequitable conduct claim into this case. As with the allegations in BDSI’s original Answer and Counterclaims (Dkt. 27), the allegations in BDSI’s Amended Counterclaims are nothing more than a desperate attempt to relitigate issues that BDSI has already unsuccessfully raised in other forums. Such tactics should not be rewarded, particularly where—as here—the allegations fall far short of the heightened pleading standards applicable to inequitable conduct, unenforceability, and unclean hands.

Inequitable conduct is typically based on allegations that a patentee withheld a material prior art reference during prosecution of a patent application with an intent to deceive the Patent Office. Overuse of the defense, which has been described as a “plague” on the patent system, prompted the Federal Circuit to narrow the defense. *Therasense, Inc. v. Becton, Dickinson and Co.* 649 F.3d 1276,

1289 (Fed. Cir. 2011) (*en banc*). In particular, the heightened pleadings standard of Federal Rule of Civil Procedure 9(b) applies to such defenses, which safeguards against inadequately pled claims or defenses and prevents parties—like BDSI here—from going on improper fishing expeditions during discovery.

BDSI's allegations are not typical allegations of inequitable conduct. Here, BDSI identifies three different individuals, including an inventor and two reputable attorneys, and would like this Court to believe that those individuals embarked on an elaborate scheme to deceive sophisticated Examiners and Judges within the Patent Office and the Patent Trial and Appeal Board ("PTAB"). This purported scheme centers around a disclosure in the '167 patent regarding regulatory requirements for content uniformity in pharmaceutical products on the one hand, and evidence submitted during an inter partes review ("IPR") of the '167 patent at the PTAB on the other hand.

All of BDSI's offensive allegations amount to disagreements with arguments that Aquestive's attorneys made in the defense of Aquestive's intellectual property rights; but attorney argument cannot form the basis for an inequitable conduct claim. Even setting aside this fundamental flaw in BDSI's pleading, BDSI has failed to plead any facts that would support a conclusion that any of the statements were material or that any of the individuals identified in BDSI's allegations had an intent to deceive the Patent Office or the PTAB. This failure is not surprising, given that BDSI has already litigated these complaints before the PTAB during the IPR proceedings that form the basis for many of its allegations; the PTAB rejected BDSI's arguments then, and this Court should summarily do the same now.

BDSI's scattershot approach should be seen for what it is—an attempt to further muddy the waters of a straightforward patent infringement case that BDSI has repeatedly delayed facing for years. Now that BDSI finally is facing the need to defend itself on the merits of infringement claims, BDSI must also comply with the pleading requirements for any counterclaim or defense it asserts.

BDSI's attempt to concoct an inequitable conduct counterclaim by re-litigating all of the prior proceedings on the '167 patent is not only inappropriate and a waste of party and court resources, but it is also legally insufficient. BDSI's inequitable conduct counterclaim must be dismissed pursuant to Rule 12(b)(6) and its corresponding affirmative defenses must be stricken pursuant to Rule 12(f) because neither the counterclaim nor the defenses meet the applicable heightened pleading requirements of Rule 9(b).

II. BACKGROUND

Aquestive filed the present suit against BDSI on November 11, 2019 alleging infringement of the '167 patent. Dkt. 1. On January 13, 2020, BDSI filed a Motion to Dismiss the Complaint. Dkt. 20. This Court denied BDSI's Motion on April 1, 2020. Dkt. 26. On April 16, 2020, BDSI filed an Answer to the Complaint and Counterclaims. Dkt. 27. Aquestive moved to dismiss BDSI's third counterclaim of unenforceability and to strike BDSI's fourth and sixth affirmative defenses of unenforceability and unclean hands, respectively. Dkt. 29. In response, BDSI filed its Amended Counterclaims. Dkt. 31.¹

Aquestive moves to dismiss BDSI's Third Counterclaim for unenforceability pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim, and to strike BDSI's Fourth and Sixth Affirmative Defenses of unenforceability and unclean hands, respectively, under Federal Rule of Civil Procedure 12(f).

A. BDSI'S THIRD COUNTERCLAIM

BDSI's Third Counterclaim alleges that the '167 patent is unenforceable based on alleged "inequitable conduct of Garry Myers, Daniel Scola, Jr., and Michael Chakansky." Amended

¹ BDSI also filed an Opposition to Aquestive's Motion to Dismiss and Aquestive's Motion to Strike. Dkt. 32. However, as explained in Aquestive's Reply, both motions are rendered moot by BDSI's Amended Answer. Dkt. 34.

Counterclaims at ¶ 50. BDSI's implausible unenforceability theory is based on various statements and alleged conduct during both the original prosecution of the '167 patent and during the IPR proceedings on the '167 patent before the PTAB. *See, e.g.*, Amended Counterclaims at ¶ 54. BDSI's Third Counterclaim identifies the following two categories of alleged misrepresentations and omissions: (1) "Intentional Misrepresentations Regarding Uniformity Requirements" (*see* Amended Counterclaims at ¶¶ 56-73); and (2) "Intentional Misrepresentations and Omissions Regarding Films and Micrographs" (*see* Amended Counterclaims at ¶¶ 74-107).

1. Allegations concerning the "Uniformity Requirements"

BDSI's allegations concerning the "Uniformity Requirements" implicate both the original prosecution leading to issuance of the '167 patent and the IPR proceedings on the '167 patent, to which BDSI itself was a party. *See id.* at ¶ 56 ("During prosecution and *inter partes* reviews of the '167 patent..."). Although BDSI's allegations include references to several additional individuals, BDSI alleges inequitable conduct on this basis only with respect to Messrs. Myers and Scola. *See* ¶ 56 ("During prosecution and *inter partes* reviews of the '167 patent, Mr. Myers and Mr. Scola knowingly misrepresented federal regulatory requirements...").

BDSI's allegations regarding the "Uniformity Requirements" in the context of the prosecution of the '167 patent begin with a quotation from the specification that "[c]urrently, as required by various world regulatory authorities, dosage forms may not vary more than 10% in the amount of active present." Amended Counterclaims at ¶ 57. BDSI attributes this statement from the patent specification to Mr. Myers based on the fact that Mr. Myers is "the first inventor" named on the '167 patent. *See id.* ("Mr. Myers represented:..."). BDSI next admits that there was no 10% uniformity requirement in the claims as filed in the original patent application (*Id.* at ¶ 59), but then describes in detail a chronological history of various rejections, responses, interviews, and amendments that ultimately resulted in issued claims that include a 10% content uniformity

requirement. *Id.* at ¶¶ 59-66. BDSI does not allege that any statement or filing by either of Messrs. Myers or Scola during prosecution was inconsistent with the '167 patent specification. Instead, BDSI alleges that the statement in the '167 patent specification is inconsistent with a statement in *a different patent*. *See, e.g., id.* at ¶67 (“In the application that led to *the '687 patent*—which, like the '167 patent, claims priority to October 12, 2001—the inventors (including Mr. Myers) represented to the Patent Office: “[c]urrently, as generally required by various world regulatory authorities, dosage forms may not vary more than 10-15% in the amount of active present.”) (emphasis added).

BDSI's allegations regarding the “Uniformity Requirements” in the IPR proceedings are limited to two paragraphs. The allegations in those paragraphs identify additional recitations of regulatory requirements for content uniformity found in the Patent Owner Response filing as well as deposition testimony given by Mr. Myers during the IPR proceedings. *See* Amended Counterclaims, at ¶¶ 69-70. In both instances, BDSI points to statements regarding an FDA 10% uniformity requirement, but baldly alleges that both statements were “misrepresentations.” *Id.*

2. Allegations concerning “Films and Micrographs”

BDSI's allegations concerning “Films and Micrographs” implicate only the IPR proceedings. *See* Amended Counterclaims at ¶ 74 (“During the *inter partes* reviews...”). As with its allegations concerning “Uniformity Requirements,” BDSI's allegations include references to several different individuals, but allege inequitable conduct only with respect to Messrs. Scola and Chakansky. *See id.* at ¶ 74 (“During the *inter partes* reviews, Messrs. Scola and Chakansky knowingly withheld material information and made material misrepresentations regarding film made by Dr. Joseph Wyse...”).

BDSI's allegations regarding “Films and Micrographs” are based on statements and conduct of Messrs. Scola and Chakansky during the IPR proceedings on the '167 patent, to which BDSI was a party. *See, e.g.,* Amended Counterclaims at ¶ 74. All of the statements identified by BDSI were

made during adversarial proceedings where Aquestive, as expected, defended the validity of its patents based on plausible arguments. BDSI's allegations include additional references to expert declarations and testimony concerning analysis of photomicrographs of prior art films that Aquestive's attorneys cited to in connection with the filings in the IPR proceedings. *Id.* at ¶¶ 75-89.

B. BDSI'S FOURTH AND SIXTH AFFIRMATIVE DEFENSES

BDSI's Fourth Affirmative Defense asserts that "[t]he '167 patent is invalid and *unenforceable* for failure to comply with one or more of the requirements of 35 U.S.C. § 101 *et seq.*, including, without limitation, sections 101, 102, 103, and/or 112." *See* Dkt. 31 at 12 (emphasis added). BDSI's Sixth Affirmative Defense asserts that "Aquestive's claims are barred by the equitable defenses of waiver, estoppel, laches, and unclean hands." *Id.* at 13. For the same reasons that BDSI's Third Counterclaim must be dismissed, Aquestive moves to strike BDSI's unenforceability defense from its Fourth Affirmative Defense and to strike BDSI's unclean hands defense from its Sixth Affirmative Defense. BDSI does not allege any facts in support of these defenses, and to the extent BDSI seeks to rely on the facts pled in support of its Third Counterclaim, those facts fail for the same reasons that they fail to allege a cognizable inequitable conduct counterclaim.

III. LEGAL STANDARD

A. Motion to Dismiss Standard under Rule 12(b)(6)

A court may grant a motion to dismiss if the complainant fails to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(6). To survive a Rule 12(b)(6) motion to dismiss, the complaint (here, counterclaim) must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). This requires "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* It demands "more than a sheer possibility that a defendant has acted unlawfully" and "more than an

unadorned, the-defendant-unlawfully-harmed-me accusation.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). If the factual allegations do not nudge the plaintiff’s claims “across the line from conceivable to plausible [the] complaint must be dismissed.” *Twombly*, 550 U.S. at 570. Further, in deciding a Rule 12(b)(6) motion to dismiss, courts “are not bound to accept as true a legal conclusion couched as a factual allegation.” *Twombly*, 550 U.S. at 555.

B. Heightened Inequitable Conduct Pleading Standard under Rule 9(b)

“Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of the patent.” *Therasense, Inc. v. Becton, Dickinson and Co.* 649 F.3d 1276 (Fed. Cir. 2011) (*en banc*). For many years, inequitable conduct defenses were the norm, and they eventually became so commonplace that the Federal Circuit criticized the practice, stating that the “habit of charging inequitable conduct in almost every major patent case has become an absolute plague.” *Therasense*, 649 F.3d at 1289; *see also id.* (“Reputable lawyers seem to feel compelled to make the charge against other reputable lawyers on the slenderest grounds.”). The Federal Circuit recognized that “courts, and the public at large have an interest in reining in inequitable conduct.” *Id.* at 1294. In an effort to reduce the frivolous assertion of inequitable conduct, the Federal Circuit narrowed the defense to specify that it requires particularized showings of both intent and materiality. *See id.* at 1290 (“[t]his court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.”).

To state a claim for inequitable conduct, a claimant must allege that “(1) an individual associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a material fact, failed to disclose material information, or submitted false material information; and (2) the individual did so with a specific intent to deceive the PTO.” *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 n.3 (Fed. Cir. 2009) (citation omitted). Inequitable conduct is subject to the heightened pleading standard under Federal Rule of Civil

Procedure 9(b). *Id.* at 1326-27. Under Rule 9(b), “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b).

In the context of an inequitable conduct claim, in order to meet the heightened pleading requirements of Rule 9(b) for the materiality prong, the claimant must “identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Exergen*, 575 F.3d at 1328; *see also* F.R.C.P. 9(b).

To meet the heightened pleading standard for the intent prong, the claimant “must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.” *Exergen*, 575 F.3d at 1328–29. The specific intent to deceive must be “the single most reasonable inference able to be drawn from the evidence.” *Therasense*, 649 F.3d at 1297. “[W]hen there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found.” *Id.* at 1290-91. For materiality, absent egregious misconduct, the doctrine “should only be applied in instances where the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim.” *Id.* at 1292.

C. Motion to Strike Standard under Rule 12(f)

Federal Rule of Civil Procedure 12(f) authorizes a court to “strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” Fed. R. Civ. P. 12(f). A court may grant a motion to strike an affirmative defense that does not meet the *Twombly/Iqbal* pleading standard. *See Racick v. Dominion Law Assoc.*, 270 F.R.D. 228, 233–34 (E.D.N.C. 2010) (following the majority of courts in this circuit that mandate the same pleading requirements for complaints as for affirmative defenses) (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Also, when an affirmative defense is based on an inequitable conduct claim,

it is subject to the same heightened pleading standard of Rule 9(b), and “will stand or fall with the inequitable conduct claim.” *Collaboration Props., Inc. v. Tandberg ASA*, 2007 WL 205065, at *7 (N.D. Cal. Jan. 25, 2007)); *see also Therasense*, 649 F.3d at 1285.

IV. BDSI’S THIRD COUNTERCLAIM SHOULD BE DISMISSED

BDSI’s far-fetched and offensive inequitable conduct theories are precisely the types of allegations that caused the Federal Circuit to narrow the defense in the first place. Through its baseless inequitable conduct allegations, BDSI is improperly asking this Court to re-litigate all of the previous ’167 patent proceedings, including BDSI’s failed attempt to invalidate the ’167 patent during the IPR proceedings. But mere dissatisfaction with the result of the IPR proceedings is not a basis to lodge serious allegations against the inventor and prosecuting patent attorneys. And it is also not a basis for further delay of the resolution of the merits of Aquestive’s infringement allegations. As this Court is aware, BDSI has engaged in a seemingly endless string of procedural maneuvers directed at its goal of avoiding infringement liability. This latest tactic is far more serious, but no less baseless, than its prior maneuvers. Indeed, the pleading requirements for inequitable conduct are not just formalities; they are serious requirements that BDSI is required to meet in order to proceed with its counterclaim. Here, BDSI has fallen woefully short of that standard.

BDSI cannot meet the stringent pleading standards for inequitable conduct because: (1) BDSI’s facts do not include the required “who, what, when, where, and how of the material misrepresentation or omission committed before the PTO” for the materiality prong (*Exergen*, 575 F.3d at 1328); and (2) there are no facts from which an intent to deceive can be plausibly derived, let alone that such intent is the only reasonable inference that can be drawn. *Therasense*, 649 F.3d at 1290-91. (“[W]hen there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found.”).

A. BDSI's Allegations Regarding "Uniformity Requirements" Do Not State a Claim for Inequitable Conduct

With respect to BDSI's allegations regarding "Uniformity Requirements," BDSI's Third Counterclaim fails to correct the deficiencies of its prior pleading for both the materiality and the intent prong of inequitable conduct.

1. BDSI's allegations do not meet the materiality prong

First, none of the allegations concerning "Uniformity Requirements" can be grounds for an inequitable conduct claim because the allegations are limited to attorney arguments presented during prosecution and IPR proceedings in favor of patentability. *See Rothman v. Target Corp.*, 556 F.3d 1310, 1328-29 (Fed. Cir. 2009) (stating that "a prosecuting attorney is free to present argument in favor of patentability without fear of committing inequitable conduct."). BDSI's recitation of the back and forth between the prosecuting attorney on the one hand and the Examiner on the other hand during prosecution reveals only that Mr. Scola properly presented arguments and amended the claims to address the Examiner's various rejections based on the prior art. *See* Amended Counterclaims at ¶¶ 59-66. Similarly, BDSI's allegations regarding the "Uniformity Requirements" during the IPR proceedings amount to nothing more than arguments presented in support of patentability in the face of prior art challenges. *Id.* at ¶¶ 69-70. Consistent with well-established Federal Circuit precedent, "district courts have not permitted inequitable conduct defenses based solely on attorney argument regarding prior art references." *Illumina, Inc. v. BGI Genomics, Co.*, Case No. 19-cv-03770-WHO, 2020 WL 571030, at *3 (N.D. Cal. Feb. 5, 2020) (collecting cases); *see also Innogenics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1379 (Fed. Cir. 2008) (holding that attorney argument cannot form the basis for inequitable conduct because prior art is submitted to the "patent examiner to examine herself, [who is] free to accept or reject the patentee's arguments distinguishing its invention from the prior art.")

Second, even setting aside BDSI's failure to include any allegations that could be grounds for an inequitable conduct claim, BDSI does not even meet its obligation to "*identify the specific who...*of the material misrepresentation or omission committed before the PTO." *Exergen*, 575 F.3d at 1328 (emphasis added). Although BDSI purports to allege inequitable conduct on the part of Messrs. Myers and Scola during prosecution of the '167 patent, a closer analysis of BDSI's allegations reveals a failure to meet the "who" requirement. As an initial matter, BDSI attributes the statements in the '167 patent specification to Mr. Myers on the grounds that he is "the first inventor," but does not otherwise provide any support for this allegation. *See* Amended Counterclaims at ¶ 57. Although BDSI next recites a chronological history of the '167 patent prosecution, BDSI's allegations are replete with vague references to other patent agents and attorneys and to Aquestive as a whole. *See id.* at ¶¶ 57 ("a patent agent"), 61 ("Julie Tabarovsky, a Hoffman & Baron attorney"), 63 ("an attorney at Hoffman & Baron"), 64 ("Aquestive amended...", "Aquestive again argued...", "Aquestive argued..."). Unable to identify the "who" element of the materiality prong, BDSI points to "[b]oth Mr. Myers and Mr. Scola." *Id.* at ¶57; *see also id.* at ¶67 ("Mr. Myers and Mr. Scola were aware—[these representations] are inconsistent with actual regulatory requirements and, indeed, differ significantly from Aquestive's other disclosures to the Patent Office."). At best, these allegations indicate that BDSI is unsure of "who" made any alleged misrepresentation, which is not sufficient to satisfy the requirements of Rule 9(b). *See Exergen*, 575 F.3d at 1327 n.3.

Third, BDSI's allegations also fail to plead the "what" element with particularity as required under Rule 9(b). Specifically, although BDSI alleges that the '167 patent specification includes a reference to 10% in the context of regulatory requirements and that the '167 patent claims were amended to include a reference to "10%," BDSI does not include any allegations to explain what specifically was a falsity, omission, or misrepresentation during the original prosecution of the '167 patent. *See* Amended Counterclaims at ¶¶ 57, 64, 67. BDSI alleges only that the statement in the

specification of the '167 patent is *inconsistent* with a statement made by Mr. Myers in connection with *a different patent*. See *id.* at ¶ 67. Therefore, BDSI yet again failed to plead any facts that, even if true, would lead to a conclusion that any statements made by Messrs. Myers or Scola amounted to a misrepresentation on which the Patent Office relied.

Fourth, BDSI's allegations are a far cry from establishing the "how" element. Essentially, BDSI argues that because the Patent Office issued the '167 patent with amended claims, the Patent Office relied on alleged misrepresentations regarding regulatory requirements for content uniformity. See Amended Counterclaims at ¶ 73 ("The misrepresentations concerning the "10%" limitation resulted in the Patent Office issuing all of the claims of the '167 Patent, including all of the asserted claims."). But, BDSI fails completely to identify "how" the Examiner would have used any particular information regarding regulatory requirements for content uniformity—to the extent that could even be considered the "what" in BDSI's allegations—in considering whether to issue the '167 patent claims. In the absence of any allegations regarding *how* the Examiner would have used the alleged omitted or misrepresented information, BDSI's allegations fail to state a claim for inequitable conduct. *Exergen*, 575 F.3d at 1329-30 (stating that a claimant must "explain both 'why' the withheld information is material and not cumulative, and 'how' an examiner would have used this information in assessing the patentability of the claims."). Similarly, with respect to the IPR proceedings, BDSI alleges only that "the claims of the '167 Patent were not canceled in the *inter partes* reviews as they should have been." Amended Counterclaims at ¶ 54. Mere dissatisfaction with its failed IPR attempt is not sufficient to plead the "how" portion of the materiality prong, and BDSI's allegations therefore fail to state a claim for inequitable conduct. See, e.g., *Exergen*, 575 F.3d at 1329-30 (affirming district court's denial of leave to amend to add inequitable conduct claim where there were factual deficiencies in pleading the "how" element of the materiality prong).

2. BDSI's allegations do not meet the intent prong

BDSI also failed adequately to plead the intent prong with respect to its allegations regarding the “10%” statements during both prosecution and the IPR proceedings. BDSI includes a single paragraph regarding the alleged intent of Messrs. Myers, Scola, and Chakansky, which includes conclusory statements regarding alleged knowledge and “specific intent to deceive.” Amended Counterclaims at ¶ 54. BDSI’s allegations are nothing more than an argument that because BDSI believes that the patent should not have issued or survived the IPR proceedings, Messrs. Myers, Scola, and Chakansky must have intentionally deceived the Examiner and PTAB into those results. But, conclusory allegations like the ones BDSI has offered here are routinely rejected as insufficient to establish the intent prong of inequitable conduct at the pleading stage. *See, e.g., Illumina*, 2020 WL 571030, at *4 (dismissing inequitable conduct claims and finding that defendant failed to plead the intent prong where defendant alleged that “because the statements to the PTAB and the Federal Circuit were demonstrably false, the attorneys and expert must have known of the falsity of these statements based on their experience and must have acted with a specific intent to deceive those bodies.”); *see also id.* (collecting cases).

Moreover, BDSI’s allegations regarding the IPR proceedings are even more implausible because they relate to arguments made in the context of adversarial proceedings to which BDSI was a party.² *See Illumina*, 2020 WL 571030, at *4-5 (rejecting defendant’s intent allegations and finding

² Moreover, like with its allegations regarding “Films and Micrographs,” *infra* Section IV.B, BDSI fails to inform the Court that it already raised arguments regarding the “10%” limitation before the PTAB during the IPR proceedings in a motion to exclude. (*See, e.g.,* Ex. B (BDSI’s Motion to Exclude), at 3-4, 11-14 (BDSI arguing for exclusion of 10% uniformity evidence based on the same testimony cited in BDSI’s Amended Answer); *see also* Ex. C (Aquestive’s Opposition to Motion to Exclude).) The PTAB denied BDSI’s motion as moot and confirmed that it did not rely on any of the statements in its decision (*See* Exhibit D (PTAB’s Final Written Decision)). Accordingly, not only do BDSI’s intent allegations fail, but BDSI has also failed to plead any set of facts under which any of its “10%” allegations can be considered material. *Illumina*, 2020 WL 571030, at *3; *see infra* Section IV.B.1.

it “implausible that [plaintiff’s] attorneys and the expert would knowingly make patently false statements about prior art that were contradicted by materials they cited and that could be readily exposed by the opposing party, and potentially even sanctioned by the tribunal”) (citing *Rothman*, 557 F.3d at 1329; *Pfizer Inc. v. Sandoz Inc.*, No. CV 12-654-GMS/MPT, 2013 WL 5934635 (D. Del. Nov. 4, 2013); *Xitronix Corp. v. KLA-Tencor Corp.*, No. 08-cv-723-SS, 2010 WL 11507169 (W.D. Tex. Oct. 27, 2010)). Because BDSI has failed to alleged any facts from which the Court could reasonably infer any intent to deceive on the part of Messrs. Myers, Scola, and Chakansky, BDSI’s allegations fail to allege the intent element of its inequitable conduct claim. *See Exergen*, 575 F.3d at 1330.

B. BDSI’s Allegations Regarding “Films and Micrographs” Do Not State a Claim for Inequitable Conduct

BDSI’s allegations regarding “Films and Micrographs” again fail to cure the deficiencies of its original attempt at asserting an inequitable conduct counterclaim in its original Answer. BDSI’s allegations amount to an attempted do-over of arguments it already raised during the IPR proceedings. The PTAB rejected those arguments the first time around, and—in doing so—confirmed that there can be no materiality or intent for any of BDSI’s allegations. According, this Court should reject BDSI’s attempt to get a second bite at the apple because it cannot meet the heightened pleading standard under Rule 9(b).

1. BDSI’s allegations do not meet the materiality prong

BDSI’s allegations regarding “Films and Micrographs” fail to allege plausibly any facts from which materiality could be established, as required by *Exergen*. BDSI alleges that Aquestive’s attorneys (Messrs. Scola and Chakansky) committed inequitable conduct during IPR proceedings, based on attorney arguments in filed documents and expert testimony from written reports and sworn

deposition testimony. *See* Amended Counterclaims at ¶¶ 75-89.³ BDSI’s allegations boil down again to a dissatisfaction with losing its attempt to invalidate the ’167 patent in IPR proceedings. As a result, BDSI wrongly resorts to accusing Messrs. Scola and Chakansky of inequitable conduct based on the arguments those attorneys made based on expert testimony. *Id.* But, courts are clear that attorney argument—particularly in adversarial proceedings such as these where BDSI itself was a party—cannot form the basis for an inequitable conduct claim. *See Rothman*, 556 F.3d 1328-29 (“a prosecuting attorney is free to present argument in favor of patentability without fear of committing inequitable conduct.”).

BDSI alleges that during the *inter partes* review of the ’167 patent, “Mr. Scola, with Mr. Chakansky, as counsel for Aquestive, filed a Patent Owner Response and two accompanying expert declarations, one from Dr. Wyse, the other from Dr. Nicholas Peppas.” Amended Counterclaims at ¶ 75. BDSI attempts to prove the alleged falsity of the statements made by Dr. Wyse and Dr. Peppas on which the “Patent Owner Response” relies by pointing to the deposition testimony provided by each expert witness. *Id.* at ¶¶ 77, 86. As a party to those proceedings, BDSI had—and took—multiple opportunities to litigate fully the veracity of the testimony it now cites in support of its inequitable conduct counterclaim, first by deposing the witnesses and then by arguing the relevance of that testimony in its reply brief and by filing a motion to exclude that same evidence. (*See, e.g.*, Ex. A (BDSI’s Reply), at 13-14 (BDSI presenting arguments regarding alleged “mystery

³ BDSI also improperly relies on an *ex parte* reexamination of the ’292 patent. Amended Counterclaims at ¶ 103. Under Federal Circuit precedent, statements made during reexamination of the ’292 patent are not relevant to the inequitable conduct inquiry on the ’167 patent unless those statements tainted the prosecution of the asserted ’167 patent. *Cordis Corp. v. Boston Sci. Corp.*, 188 F. App’x 984, 989 (Fed. Cir. 2006) (“The relevant inquiry is whether the ‘inequitable conduct in prosecuting the [parent] patent had immediate and necessary relation to the ... enforcement of the [child] patents.’”) (citing *Consol. Aluminum Corp. v. Foseco Int’l Ltd.*, 910 F.2d 804, 810-11 (Fed. Cir. 1990)). BDSI has made no such allegations. *See* Amended Counterclaims at ¶¶ 48-75; *see also id.* at ¶¶ 1-47 (incorporated by reference through par. 48).

photomicrographs”); Ex. B (BDSI’s Motion to Exclude), at 1-3, 11 (BDSI arguing that the “mystery photomicrographs” should be excluded); *see also* Ex. C (Aquestive’s Opposition to Motion to Exclude).) But, the following statement from the PTAB’s Final Written Decision directly contradicts the arguments BDSI seeks to re-litigate here:⁴

“[BDSI] moves to exclude the Peppas Declaration (Ex. 2002), the Wyse Declaration (Ex. 2003), the Myers Declaration (Ex. 2004), and the Lin Declaration (Ex. 2005). See generally Pet. Mot. to Exclude. ***Our decision does not rely on those declarations.*** Accordingly, we ***dismiss Petitioner’s Motion to Exclude as moot.***”

(*See* Exhibit D (PTAB’s Final Written Decision).)

The PTAB’s statement confirms that it did not even consider the evidence from these witnesses in upholding the validity of the ’167 patent. Accordingly, BDSI did not identify what claims of the ’167 patent could have been affected by the cited testimony, and it did not—because it cannot—identify how the PTAB relied on it. There is simply no set of facts under which the alleged deposition testimony could be considered material for purposes of any inequitable conduct claim. *See, e.g., Illumina*, 2020 WL 571030, at *3 (striking inequitable conduct defense without leave to amend where defense was based on prior proceedings before the PTAB and stating that “[t]he underlying decisions of the PTAB and Federal Circuit reinforce [the court’s] conclusion that each of the allegedly false statements was permissible attorney argument and also indicate that some or all of the statements were not material to those courts’ decisions.”).

⁴ In the context of a motion to dismiss, the Court is not required to accept factual allegations “that contradict matters properly subject to judicial notice or by exhibit.” *Veney v. Wyche*, 293 F.3d 726, 730 (4th Cir. 2002). The PTAB’s Final Written Decision and the briefing on BDSI’s Motion to Exclude contradict the documents BDSI cited in its counterclaim, which may be considered even on a motion to dismiss under Fed. R. Civ. P. 12(b)(6). *See Reaves v. Hagel*, 2013 WL 5674981, at *4 n.2 (E.D.N.C. Oct. 17, 2013) (citing *Phillips v. LCI Int’l, Inc.*, 190 F.3d 609, 618 (4th Cir. 1999)).

2. BDSI's allegations do not meet the intent prong

Despite including several conclusory paragraphs regarding the alleged intent to deceive the PTAB (*see* Amended Counterclaims at ¶¶ 100-104), BDSI's allegations also fail to allege plausibly that a specific intent to deceive is the "single most reasonable inference that can be drawn from the evidence." *Therasense*, 649 F.3d at 1297. The context of BDSI's allegations is relevant to whether BDSI has plausibly alleged intent; in fact, it confirms that BDSI's conclusory allegations are insufficient to allege plausibly an intent to deceive on the part of either Mr. Scola or Mr. Chakansky. *See Illumina*, 2020 WL 571030, at *4 (finding that conclusory allegations do not adequately plead knowledge or intent and acknowledging that in the context of adversarial proceedings, "rigorous advocacy would require [plaintiff's] legal team to advance all plausible arguments before the tribunals and opposing counsel to attack those arguments."). To the extent BDSI believed that any attorney or witness violated its duty of candor to the PTAB, that issue could have been raised by either BDSI or the PTAB at the time. *See* 37 C.F.R. § 42.11(d). BDSI, armed with all of the facts it seeks in desperation to re-litigate here, opted only to file a motion to exclude the evidence, and the PTAB rejected that motion. *Illumina*, 2020 WL 571030, at *3 (striking inequitable conduct defense based on attorney argument in prior PTAB proceedings and noting that "there was no attempt to sanction [patentee]'s legal team during the prior proceedings"). There is no basis for the Court to entertain frivolous allegations that BDSI has already tried, and failed, to litigate before the PTAB.

BDSI's allegations fall grossly short of the heightened inequitable conduct pleading standard. BDSI's claim of inequitable conduct should be dismissed without leave to amend.

V. BDSI'S FOURTH AND SIXTH AFFIRMATIVE DEFENSES OF UNENFORCEABILITY AND UNCLEAN HANDS SHOULD BE STRICKEN

In its Answer, BDSI includes a long list of affirmative defenses, each comprising a single sentence and none supported by any factual allegations. Aquestive moves to strike BDSI's Fourth

and Sixth Affirmative Defenses.

BDSI's Fourth Affirmative Defense conspicuously includes the word "unenforceability." To the extent BDSI's Fourth Affirmative Defense relates to the unenforceability theory of BDSI's Third Counterclaim, it should be stricken pursuant to Rule 12(f) for failure to meet the heightened pleading standard of Rule 9(b) for the same reasons as discussed in Section IV, *supra*. See *Collaboration Props., Inc.*, 2007 WL 205065, at *7 (affirmative defenses based on an inequitable conduct claim are subject to Rule 9(b) and "will stand or fall with the inequitable conduct claim."); see also *Therasense*, 649 F.3d at 1285.

BDSI's sixth affirmative defense alleges that "Aquestive's claims are barred by the equitable doctrines of waiver, estoppel, laches, and unclean hands." BDSI's unclean hands defense should also be stricken pursuant to Rule 12(f) because, to the extent there are any facts to support the defense, they are the same inadequate facts BDSI plead for its inequitable conduct counterclaim. See Section IV *supra*. Those inadequate facts do not meet the heightened pleading requirements for unclean hands, whether presented as a claim or as a defense.

VI. CONCLUSION

For the reasons given above, Aquestive respectfully requests that the Court dismiss with prejudice BDSI's Third Counterclaim for failure to plausibly state a claim under Rule 12(b)(6), and strike BDSI's Fourth and Sixth affirmative defenses under Rule 12(f).

Dated: June 25, 2020

Respectfully submitted,

By: /s/ E. Bradley Evans

E. Bradley Evans
N.C. State Bar I.D. No.:28515
Email: ebe@wardansmith.com
Joseph A. Schouten
N.C. State Bar I.D. No.: 39430
Email: jas@wardansmith.com
WARD AND SMITH, P.A.
Post Office Box 8088
Greenville, NC 27835-8088
Phone: 252-215-4025
Fax: 252-215-4077

*Local Civil Rule 83.1 Counsel for
Plaintiff Aquestive Therapeutics, Inc.*

By: James F. Hibey

James F. Hibey
STEPTOE & JOHNSON LLP
1330 Connecticut Avenue, N.W.
Washington, D.C. 20036
(202) 429-6407
jhibey@steptoe.com
kcappaert@steptoe.com

John L. Abramic
Anna M. Targowska*
STEPTOE & JOHNSON LLP
227 W. Monroe St., Suite 4700
Chicago, Illinois 60606
(312) 577-1300
jabramic@steptoe.com
atargowska@steptoe.com

Jamie L. Lucia
STEPTOE & JOHNSON LLP
One Market Plaza
Spear Tower, Suite 3900
San Francisco, California 94105
(415) 365-6711
jlucia@steptoe.com

*Attorneys for Plaintiff
Aquestive Therapeutics, Inc.*

* CM/ECF Registration Forthcoming

ND: 4841-9289-7217, v. 1